

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

ARCARE, INC.

Plaintiff,

v.

DUCHESNAY USA

Defendant.

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Case No.: _____

DEFENDANT’S NOTICE OF REMOVAL

Defendant Duchesnay USA, Inc. (“Defendant”), by and through the undersigned counsel, hereby removes Case No. 2019-06950, *Arcare, Inc. v. Duchesnay USA*, an action pending in the Court of Common Pleas of Montgomery County, Pennsylvania, to the United States District Court for the Eastern District of Pennsylvania. Defendant removes the State Court Action under 28 U.S.C. §§ 1331, 1441, and 1446, on the factual and legal grounds discussed below.

I. Background

1. On January 28, 2019, Plaintiff Arcare, Inc. (“Plaintiff”) filed a Class Action Complaint (the “Complaint”) against Defendant in the Court of Common Pleas of Montgomery County, Pennsylvania, captioned *Arcare, Inc. v. Duchesnay USA*, Case No. 2019-06950 (the “State Court Action”).

2. Defendant was served with a copy of the Summons and Complaint on or about May 15, 2019. *See* Exhibit A.

3. Plaintiff alleges that Defendant violated the Telephone Consumer Protection Act (“TCPA”), 47 U.S.C. § 227.

4. This Court has original jurisdiction over this matter pursuant to 28 U.S.C. § 1331, as the TCPA arises under the Constitution, laws, or treaties of the United States. *Mims v. Arrow Fin. Svcs., LLC*, 565 U.S. 368 (2012).

II. Venue

5. The State Court Action is being removed from the Court of Common Pleas of Montgomery County, Pennsylvania, which is within the Eastern District of Pennsylvania. Thus, venue is proper pursuant to 28 U.S.C. § 98 because it is the “district and division embracing the place where the action is pending.” *See* 28 U.S.C. § 1441(a).

III. Procedure for Removal

6. Defendant was served with the Summons and Complaint on or about May 15, 2019. *See* Exhibit A. This Notice of Removal is timely because it is being filed within 30 days of Defendant’s receipt of the Summons and Complaint, and within one year of the commencement of this action. 28 U.S.C. § 1446(b); *Murphy Bros., Inc. v. Michetti Pipe Stringing, Inc.*, 526 U.S. 344, 354 (1999) (explaining that the time for filing a notice of removal does not run until a party has been served with the summons and complaint under the applicable state law).

7. Pursuant to 28 U.S.C. § 1446(d), Defendant will promptly provide written notice of removal of this action to Plaintiff, and will promptly file a copy of this Notice of Removal with the Clerk of the Court of Common Pleas of Montgomery County, Pennsylvania.

8. A copy of all process, pleadings, and orders served upon Defendant is attached hereto as Exhibit A in accordance with 28 U.S.C. § 1446(a).

9. For all of the foregoing reasons, this Court has original jurisdiction over this lawsuit pursuant to 28 U.S.C. §§ 1331, 1441, and 1446, and removal is proper.

10. In submitting this Notice of Removal, Defendant reserves all defenses, including but not limited to, whether Plaintiff has standing and whether its complaint states a claim for which relief can be granted.

WHEREFORE, Defendant respectfully requests that the above action now pending in the Court of Common Pleas of Montgomery County, Pennsylvania, Case No. 2019-06950, be removed to the United States District Court for the Eastern District of Pennsylvania.

Dated: June 14, 2019

Respectfully Submitted,



Ezra D. Church
Kristin M. Hadgis
Morgan, Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103
Phone: (215) 963-5000
Fax: (215) 963-5001
ezra.church@morganlewis.com
kristin.hadgis@morganlewis.com

Counsel for Defendant Duchesnay USA, Inc.

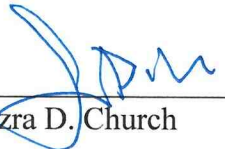
CERTIFICATE OF SERVICE

I hereby certify that on June 14, 2019, the foregoing was served upon the following by
United States Mail, postage prepaid and via electronic mail:

Kenneth J. Grunfeld, Esq.
Golomb & Honik
1835 Market Street, Suite 2900
Philadelphia, PA 19103
kgrunfeld@golombhonik.com

Randall K. Pulliam, Esq.
Lee Lowther, Esq.
Carney Bates & Pulliam, PLLC
519 West 7th Street
Little Rock, Arkansas 72201
rpulliam@cbplaw.com
llowther@cbplaw.com

Counsel for Plaintiff



Ezra D. Church

EXHIBIT A

GOLOMB & HONIK
BY: KENNETH J. GRUNFELD, ESQUIRE
Identification No.: 84121
1835 Market Street, Suite 2900
Philadelphia, PA 19103
(215) 985-9177

Attorney for Plaintiff

ARCARE, INC.

Plaintiff,
vs.

DUCHESNAY USA,

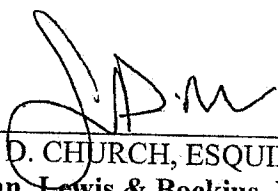
Defendant

IN THE COURT OF COMMON PLEAS
OF MONTGOMERY COUNTY

NO: 2019-06950

ACCEPTANCE OF SERVICE

I, Ezra D. Church, Esquire, of the law firm of Morgan, Lewis & Bockius LLP, as counsel for the Defendant, Duchesnay USA, Inc. do hereby accept service of Plaintiff's Civil Action Complaint, service effective as of May 15, 2019. The complaint was originally filed with Court on April 12, 2019 and reinstated on May 3, 2019.


EZRA D. CHURCH, ESQUIRE
Morgan, Lewis & Bockius, LLP
1701 Market Street
Philadelphia, PA 19103

Attorney for Defendant Duchesnay USA, Inc.

Date: _____

June 11, 2019

GOLOMB & HONIK, P.C.

BY: KENNETH J. GRUNFELD, ESQUIRE

Identification No.: 84121

1835 Market Street, Suite 2900

Philadelphia, PA 19103

(215) 985-9177

-and-

CARNEY BATES & PULLIAM, PLLC

BY: RANDALL K. PULLIAM, ESQUIRE

(*pro hac* pending)

BY: E. LEE LOWTHER III, ESQUIRE

(*pro hac* pending)

519 West 7th Street

Little Rock, Arkansas 72201

(501) 312-8500

Attorneys for Plaintiff

ARCARE, INC.

117 South 2nd Street

Augusta, AR 72006

Plaintiff,

vs.

DUCHESNAY USA

919 Conestoga Road

Building One, Suite 203

Rosemont, PA 19010

Defendant

IN THE COURT OF COMMON PLEAS
OF MONTGOMERY COUNTY

NO:

CLASS ACTION COMPLAINT

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER OR IF YOU CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP

Montgomery County Bar Association
100 W. Airy Streets
P.O. Box 268
Norristown, PA 19404
(610) 279-9660

AVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte (20) dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademas, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades y otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO INMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO. VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

Montgomery County Bar Association
101 W. Airy Street
P.O. Box 268
Norristown, PA 19404
(610) 279-9660

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Attorneys for Plaintiff

ARCARE, INC.

117 South 2nd Street

Augusta, AR 72006

Plaintiff,

vs.

DUCHESNAY USA

919 Conestoga Road

Building One, Suite 203

Rosemont, PA 19010

Defendant

IN THE COURT OF COMMON PLEAS
OF MONTGOMERY COUNTY

NO:

CLASS ACTION COMPLAINT

Plaintiff ARcare, Inc. ("Plaintiff"), on behalf of itself and all others similarly situated, brings this Complaint against Duchesnay USA, Inc. ("Duchesnay"), for violations of the Telephone Consumer Protection Act. Plaintiff seeks certification of its claims against Defendant as a class action. In support, Plaintiff states as follows:

INTRODUCTION

1. This case challenges Defendant's policy and practice of faxing unsolicited advertisements. In or around April 2018, Defendant faxed an unsolicited and unwanted advertisement to Plaintiff which is attached as Exhibit A.

2. Congress enacted the Telephone Consumer Protection Act ("TCPA"), 47 U.S.C. § 227, to regulate the fast-growing expansion of the telemarketing industry. As is pertinent here, the TCPA and its implementing regulations prohibit persons within the United States from sending advertisements via fax.

3. Junk faxes disrupt recipients' peace, drain recipients' paper, ink, and toner, and cause recipients' tangible damages. Junk faxes also cause recipients to waste valuable time retrieving and discerning the purpose of the faxes; prevent fax machines from receiving and sending authorized faxes; and cause undue wear and tear on recipients' fax machines. Plaintiff offers clinical and pharmaceutical services and must use its fax machine to receive communications about patients, including vital information such as prescriptions and insurance information. That purpose is impeded when Plaintiff's fax machine is invaded by junk faxes. As recognized by Congress in enacting the TCPA, junk faxes are a significant problem interfering with modern commerce. As discussed below, this is particularly true for healthcare providers like ARcare, which still rely significantly on faxes to communicate vital information about patients such as prescriptions and insurance information.

4. ARcare is a healthcare provider that was established in 1986. ARcare provides medical and pharmacy services through its more than thirty locations, which are primarily in rural areas in Arkansas. ARcare operates family practices, specialized medical care such as cardiology and chronic disease treatment, dental practices, and pharmacies. As a medical provider, ARcare relies upon fax machines to operate and provide services to its patients. ARcare conservatively

estimates that it receives several thousand unwanted and unsolicited faxes each year. ARcare must wade through dozens of unsolicited faxes from pharmaceutical and other companies selling their products to find vital incoming faxes, such as prescription refills and insurance authorizations. It was this harm that Congress recognized in passing the Telephone Consumer Protection Act, 47 U.S.C. § 227 (“TCPA”).¹

5. The TCPA provides a private right of action and statutory damages of \$500 per violation, which may be trebled when the violation is willful or knowing.

6. On behalf of itself and all others similarly situated, Plaintiff brings this case under the TCPA to recover declaratory relief, damages for violations of the TCPA, and an injunction prohibiting Defendants from future TCPA violations.

JURISDICTION AND VENUE

7. This Court has general personal jurisdiction over Defendant because its principal place of business is in Bryn Mawr, Pennsylvania.²

8. Venue in this county because it is where Defendant’s principal place of business is located.

¹ “Unsolicited advertising is beginning to clog fax lines, restricting the owners’ ability to use their machines for the purposes they originally bought them for and generating operating costs the users can’t control. Unlike junk mail, which can be discarded, or solicitation phone calls, which can be refused or hung up, junk fax ties up the recipient’s line until it has been received and printed. The recipient’s machine is unavailable for business and he or she incurs the high cost for supplies before knowing whether the message is either wanted or needed.” 135 Cong. Rec. E 1462 (May 2, 1989, statement of Rep. Edward Markey, 101 Cong.) Representative Markey further testified: “To quote an article from the Washington Post, ‘receiving junk fax is like getting junk mail with postage due.’ Succinctly put, using a facsimile machine to send unsolicited advertising not only shifts costs from the advertiser to the recipient, but keeps an important business machine from being used for its intended purpose.” 136 Cong. R. H 5818 (July 30, 1990), 101st Cong. 2nd Sess., statement of Rep. Markey, p. 5).

² Some of Defendant’s online materials list its address as the unincorporated town of Rosemont, Pennsylvania, while other materials list Bryn Mawr, Pennsylvania. Either way, general personal jurisdiction may be exercised over Defendant in Pennsylvania, and venue is proper in this Court.

PARTIES

9. Plaintiff ARcare is an Arkansas non-profit corporation located in Augusta, Arkansas.

10. Defendant is a corporation formed under the laws of the State of Delaware and which has its principal place of business in Bryn Mawr, Pennsylvania. Defendant's business is the manufacture and distribution of pharmaceuticals.

FACTS

11. On or around April 1, 2018, Defendant sent an unsolicited advertisement to Plaintiff's ink-and-paper facsimile machine located at its corporate office in Augusta, Woodruff County, Arkansas. The advertisement advertised the commercial availability of Defendant's drug Bonjesta: "INTRODUCING A NEW FDA-Approved prescription treatment for Nausea and Vomiting of Pregnancy when conservative management fails." The fax, too, included information on distributors from whom Bonjesta could be purchased, touted the drug as "Accessible and affordable," and included an "Indication" description of who should be considered for the drug. A copy of this facsimile is attached hereto and marked as Exhibit A.

12. Upon information and belief, Plaintiff has received multiple fax advertisements from Defendant similar to Exhibit A.³ The majority of junk faxes received by ARcare, similar to those received by all Class Members, are immediately thrown into the trash. Accordingly, not all faxes received by ARcare during the statutory period have been retained. Exhibit A is similar to these additional faxes, because upon information and belief, Defendant sent additional unsolicited faxes advertising its products but not necessarily these *exact* faxes.

³ Given that such faxes are junk faxes, ARcare does not retain them. ARcare anticipates that discovery will demonstrate that Defendants have sent multiple fax advertisements to ARcare similar to Exhibit A

13. Defendant did not have Plaintiff's prior express invitation or permission to send advertisements to Plaintiff's fax machine.

CLASS ALLEGATIONS

14. In accordance with Pa. R.C.P. No. 1701, *et seq.*, Plaintiff brings this action on behalf of the following class of persons (the "Class"):

All persons and entities who held telephone numbers that received one or more telephone facsimile transmissions that promoted the commercial availability or quality of property, goods, or services offered by Duchesnay USA, Inc.

15. Plaintiff reserves the right to modify or amend the definition of the proposed Class before the Court determines whether certification is proper, as more information is gleaned in discovery.

16. Excluded from the Class are Defendant, any parent, subsidiary, affiliate, or controlled person of Defendant, as well as the officers, directors, agents, servants, or employees of Defendant and the immediate family members of any such person. Also excluded are any judge who may preside over this case and any attorneys representing Plaintiff or the Class.

17. Numerosity. The Members of the Class are so numerous that joinder is impractical. Upon information and belief, Defendant has sent illegal fax advertisements to hundreds if not thousands of other recipients.

18. Commonality. Common questions of law and fact apply to the claims of all Class Members and include (but are not limited to) the following:

- (a) Whether Defendant sent faxes advertising the commercial availability of property, goods, or services;
- (b) The manner and method Defendant used to compile or obtain the list of fax numbers to which it sent Exhibit A as well as other fax advertisements;

- (c) Whether Defendant faxed advertisements without first obtaining the recipient's prior express permission or invitation;
- (d) Whether Defendant sent the fax advertisements knowingly or willfully;
- (e) Whether Defendant violated 47 U.S.C. § 227;
- (f) Whether Plaintiff and the other Class Members are entitled to actual and/or statutory damages;
- (g) Whether the Court should award treble damages; and
- (h) Whether Plaintiff and the other Class Members are entitled to declaratory, injunctive, and/or other equitable relief.

19. Typicality. Plaintiff's claims are typical of the claims of all Class Members. Plaintiff received an unsolicited fax advertisement from Defendant during the Class Period. Plaintiff makes the same claims that it makes for the Class Members and seeks the same relief that it seeks for the Class Members. Defendant has acted in the same manner toward Plaintiff and all Class Members.

20. Fair and Adequate Representation. Plaintiff will fairly and adequately represent and protect the interests of the Class. It is interested in this matter, has no conflicts, and has retained experienced class counsel to represent the Class. Counsel for plaintiffs have agreed, consistent with the Pennsylvania Rules of Professional Conduct, specifically Rule 1.8(e)(1), to advance the court costs and expenses of litigation on their behalf, contingent on the outcome of this litigation.

21. Predominance and Superiority. For the following reasons, common questions of law and fact predominate, and a class action is superior to other methods of adjudication:

- (a) Proof of Plaintiff's claims will also prove the claims of the Class without the need for separate or individualized proceedings;
- (b) Evidence regarding defenses or any exceptions to liability that Defendant may assert will come from Defendant's records and will not require individualized or separate inquiries or proceedings;

- (c) Defendant has acted and continues to act pursuant to common policies or practices in the same or similar manner with respect to all Class Members;
- (d) The amount likely to be recovered by individual Members of the Class does not support individual litigation. A class action will permit a large number of relatively small claims involving virtually identical facts and legal issues to be resolved efficiently in one proceeding based on common proof;
- (e) This case is inherently well-suited to class treatment in that:
 - (i) Defendant identified persons or entities to receive its fax transmissions, and it is believed that Defendant's computer and business records will enable Plaintiff to readily identify Class Members and establish liability and damages;
 - (ii) Common proof can establish Defendant's liability and the damages owed to Plaintiff and the Class;
 - (iii) Statutory damages are provided for in the statutes and are the same for all Class Members and can be calculated in the same or a similar manner;
 - (iv) A class action will result in an orderly and expeditious administration of claims, and it will foster economies of time, effort, and expense;
 - (v) A class action will contribute to uniformity of decisions concerning Defendant's practices; and
 - (vi) As a practical matter, the claims of the Class are likely to go unaddressed absent class certification.

CLAIM FOR RELIEF

COUNT I

Violations of the Telephone Consumer Protection Act 47 U.S.C. § 227(b)(1)(C) and 47 C.F.R. § 64.1200(a)(4)

22. Plaintiff hereby incorporates by reference each of the preceding paragraphs as though fully set forth herein.

23. The TCPA provides strict liability for sending fax advertisements in a manner that does not comply with the statute. Recipients of fax advertisements have a private right of action

to seek an injunction or damages for violations of the TCPA and its implementing regulations. 47 U.S.C. § 227(b)(3).

24. The TCPA makes it unlawful to send any “unsolicited advertisement” via fax unless certain conditions are present. 47 U.S.C. § 227(b)(1)(C). “Unsolicited advertisement” is defined as “any material advertising the commercial availability or quality of any property, goods, or services which is transmitted to any person without that person’s prior express invitation or permission, in writing or otherwise.” 47 U.S.C. § 227(a)(5).

25. Unsolicited faxes are illegal if the sender and recipient do not have an “established business relationship.” 47 U.S.C. § 227(b)(1)(C)(i). “Established business relationship” is defined as “a prior or existing relationship formed by a voluntary two-way communication between a person or entity and a business or residential subscriber with or without an exchange of consideration, on the basis of an inquiry, application, purchase or transaction by the business or residential subscriber regarding products or services offered by such person or entity, which relationship has not been previously terminated by either party.” 47 U.S.C. § 227(a)(2); 47 C.F.R. § 64.1200(f)(6).

26. Regardless of whether the sender and recipient have an established business relationship, a faxed advertisement is illegal unless it includes an opt-out notice on its first page that complies with the TCPA’s requirements. *See* 47 U.S.C. § 227(b)(1)(C)(iii); 47 C.F.R. § 64.1200(a)(4)(iv). To comply with the law, an opt-out notice must (1) inform the recipient that the recipient may opt out of receiving future faxes by contacting the sender; (2) provide both a domestic telephone number and a facsimile machine number—one of which must be cost-free—that the recipient may contact to opt out of future faxes; and (3) inform the recipient that the sender’s failure to comply with an opt-out request within thirty days is a violation of law. *See* 47 U.S.C. § 227(b)(2)(D); 47 CFR § 64.1200(a)(4)(iii).

27. Defendant faxed unsolicited advertisements to Plaintiff in violation of 47 U.S.C. § 227(b)(1)(C) and 47 C.F.R. § 64.1200(a)(4).

28. Defendant knew or should have known (a) that Plaintiff had not given express invitation or permission for Defendant to fax advertisements about its products; and (b) that Exhibit A is an advertisement.

29. Defendant's actions caused actual damage to Plaintiff and the Class Members. Defendant's junk faxes caused Plaintiff and the Class Members to lose paper, toner, and ink consumed in the printing of Defendant's faxes through Plaintiff's and the Class Members' fax machines. Defendant's faxes cost Plaintiff and the Class Members time that otherwise would have been spent on Plaintiff's and the Class Members' business activities.

30. In addition to statutory damages (and the trebling thereof), Plaintiff and the Class are entitled to declaratory and injunctive relief under the TCPA.

REQUEST FOR RELIEF

WHEREFORE Plaintiff, individually and on behalf of all others similarly situated, respectfully requests that this Court:

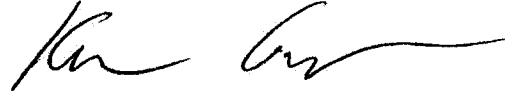
- a) Determine that this action may be maintained as a class action under Pa. R.C.P. No. 1701, *et seq.*;
- b) Declare Defendant's conduct to be unlawful under the TCPA;
- c) Award damages under the TCPA for each violation in the amount of actual monetary loss or \$500, whichever is greater, and treble those damages;
- d) Enjoin Defendant from additional violations;
- e) Award Plaintiff and the Class their attorney's fees and costs;
- f) Grant such other legal and equitable relief as the Court may deem appropriate, including costs and attorney's fees.

JURY DEMAND

Plaintiff and the Members of the Class hereby request a trial by jury.

Respectfully submitted,

GOLOMB & HONIK, P.C.



KENNETH J. GRUNFELD, ESQUIRE
RANDALL K. PULLIAM, ESQUIRE
E. LEE HIGHTOWER, III, ESQUIRE
Attorneys for Plaintiff

Date: April 11, 2019

VERIFICATION

ARCARE, INC. hereby states that it is the Plaintiff in this action and verifies that the statements made in the foregoing **CLASS ACTION COMPLAINT** are true and correct to the best of its knowledge, information and belief. The undersigned understands that the statements therein are made subject to penalties of 18 Pa. C.S. Section 4904 relating to unsworn falsification to authorities.



Dr. Steven F. Collier

**On behalf of:
ARCARE, INC.**

Date: April 5, 2019

EXHIBIT A

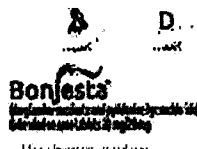
Bonjesta
(doxylamine succinate and pyridoxine hydrochloride)
Extended-release tablets 20 mg/20 mg

**INTRODUCING A NEW FDA-Approved prescription treatment
for Nausea and Vomiting of Pregnancy when conservative
management fails.**

NOW AVAILABLE:

BONJESTA® - a multilayer, extended-release formulation of Diclegis® (doxylamine succinate and pyridoxine hydrochloride) offering the same proven safety and efficacy, but with simpler dosing and reduced pill burden.

- Fast-acting, long-lasting formulation is designed for both immediate and continuous relief throughout the day and night when taken as prescribed.
- Accessible and affordable - costs less than Diclegis® for most patients.

NDC Number	UPC Number	Description	Size	WAC	Storage Guidelines	Image
55494-120-60	3-55494-120-60-5	20 mg doxylamine succinate and 20 mg pyridoxine hydrochloride	60 tablets/ bottle	\$617.40/ bottle	Bonjesta® should be stored at controlled room temperatures of 20°C to 25°C (68°F to 77°F); allows for excursions between 15°C and 30°C (59°F and 86°F).	

Wholesaler Name	Item Number
AmerisourceBergen	10185371
Cardinal	5435888
McKesson	3780392

INDICATION

Bonjesta® is a fixed-dose combination drug product of 20 mg doxylamine succinate, an antihistamine, and 20 mg pyridoxine hydrochloride, a vitamin B6 analog, indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

LIMITATIONS OF USE

Bonjesta® has not been studied in women with hyperemesis gravidarum.

SELECT SAFETY INFORMATION

Bonjesta® is contraindicated in women with known hypersensitivity to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride, or any inactive ingredient in the formulation. Bonjesta® is also contraindicated in combination with monoamine oxidase inhibitors (MAOIs) as MAOIs intensify and prolong the adverse central nervous system (CNS) effects of Bonjesta®. Use of MAOIs may also prolong and intensify the adverse CNS effects (the anticholinergic effects) of antihistamines.

Bonjesta® may cause somnolence due to the anticholinergic properties of doxylamine succinate, an antihistamine. Women should avoid engaging in activities requiring complete mental alertness, such as driving or operating heavy machinery, while using Bonjesta® until cleared to do so by their healthcare provider.

Use of Bonjesta® is not recommended if a woman is concurrently using CNS depressants, such as alcohol or sedating medications, including other antihistamines (present in some cough and cold medications), opiates, and sleep aids. The combination of Bonjesta® and CNS depressants could result in severe drowsiness leading to falls or other accidents.


DUCHESNAY USA

www.bonjesta.com

Please see Important Safety Information on reverse

Bon-2018-0038-01 Apr 2018



IMPORTANT SAFETY INFORMATION

INDICATION

Bonjesta® is a fixed-dose combination drug product of 20 mg doxylamine succinate, an antihistamine, and 20 mg pyridoxine hydrochloride, a vitamin B6 analog, indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

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Use of Bonjesta® is not recommended if a woman is concurrently using CNS depressants, such as alcohol or sedating medications, including other antihistamines (present in some cough and cold medications), opiates, and sleep aids. The combination of Bonjesta® and CNS depressants could result in severe drowsiness leading to falls or other accidents.

A food-effect trial demonstrated that the delay in the onset of action of Bonjesta® may be further delayed, and a reduction in absorption may occur when tablets are taken with food. Therefore, Bonjesta® should be taken on an empty stomach with a glass of water.

Bonjesta® has anticholinergic properties and should be used with caution in women who have: (1) asthma, (2) increased intraocular pressure, (3) narrow angle glaucoma, (4) a stenosing peptic ulcer, (5) pyloroduodenal obstruction, or (6) bladder-neck obstruction.

The most common adverse reaction (≥5 percent and exceeding the rate in placebo) with combination 10 mg doxylamine succinate and 10 mg pyridoxine hydrochloride tablets is somnolence.

The safety and effectiveness of Bonjesta® in children under 18 years of age have not been established. Fatalities have been reported from doxylamine overdose in children. Children appear to be at a high risk for cardiorespiratory arrest.

Bonjesta® is intended for use in pregnant women.

Women should not breastfeed while using Bonjesta® because the antihistamine component (doxylamine succinate) in Bonjesta® can pass into breast milk. Excitement, irritability, and sedation have been reported in nursing infants presumably exposed to doxylamine succinate through breast milk. Infants with apnea or other respiratory syndromes may be particularly vulnerable to the sedative effects of Bonjesta® resulting in worsening of their apnea or respiratory conditions.

Bonjesta® is an **extended-release formulation**; therefore, signs and symptoms of **intoxication** may **not be apparent immediately**. Signs and symptoms of overdose may include restlessness, dryness of mouth, dilated pupils, sleepiness, vertigo, mental confusion, and tachycardia. At toxic doses, doxylamine exhibits anticholinergic effects, including seizures, rhabdomyolysis, acute renal failure and death. If treatment is needed, it consists of gastric lavage or activated charcoal, whole bowel irrigation and symptomatic treatment. If you suspect an overdose or seek additional information about overdose treatment, call a poison control center at 1-800-222-1222.

To report suspected adverse reactions, contact Duchesnay Inc. at 1-855-722-7734 or medicalinfo@duchesnayusa.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References:

1. Bonjesta® Prescribing Information, Bryn Mawr, PA: Duchesnay USA Inc., 2017.
2. Diclegis® Prescribing Information, Bryn Mawr, PA: Duchesnay USA Inc., 2013.
3. Costantine, M. M., et al. Determinants of adherence to delayed-release doxylamine and pyridoxine in patients with nausea and vomiting of pregnancy. *Ther Drug Monit.* 2012; 34:569-573.